REMARKS

Reconsideration is requested.

Claims 12-34 are pending. Claim 17 has been amended, without prejudice, to include the details described by the Examiner on page 3 of the Office Action dated March 5, 2008. Claim 34 has been added to continue the pendency of unamended claim 17. No new matter has been added. Claim 21 has been withdrawn from consideration. Rejoinder and allowance of any claim defining a method of making and/or using a product defined by an allowable claim, at an appropriate time, are requested.

The Section 112, first paragraph "enablement", rejection of claim 17 is believed to be obviated by the above amendment. Claim 17 has been amended above, without prejudice, to advance prosecution. Reconsideration and withdrawal of the rejection are requested.

The Examiner acknowledges that the same rejection had been previously made and previously withdrawn. The basis for reasserting the rejection is not clearly stated and clarification is requested in the event the rejection is again maintained, such as against claim 34.

The claimed invention, to a medicament, is acknowledged by the Examiner to be supported by the specification for at least the use of the composition as an immunogenic composition. The Examiner appears to believe that the specification must teach how to use the claimed composition in the "diagnostics, mitigation, treatment, cure, or prevention of disease in humans or other animals" to demonstrate enablement

for the claimed medicament. The Examiner also appears to require *in* vivo clinical data to demonstrate that one of ordinary skill in the art can use the claimed medicament. See page 3 of the Office Action dated March 5, 2008.

The Examiner's comments suggest that the Examiner believes that a claim to a "medicament" is too broad to allegedly be supported by the specificaiton whereas claims to an immunogenic composition is supported by an enabling disclosure.

The Examiner is requested to appreciate that similar issues were before the Court of Customs and Patent Appeals in In re Anderson, 176 USPQ 331, 334-335 (C.C.P.A. 1973), wherein the court reversed the rejection and explained as follows:

> The concept of medicament or medication involves a highly technical subject in an art requiring a high degree of technical skill—doctors of medicine and pharmacologists. It is common knowledge that some medicines of great utility are lethal when used in the wrong quantity, that one man's medicine is another man's poison, and that what is good medicine in one place may be bad medicine in another. The board, seemingly, is demanding a claim limitation to operative medicaments in operative quantity. We think that dependent claims such as the above, which merely add a limitation to the two-layer combination dressing by calling for medication in the primary layer, are inherently limited—by common sense if nothing else—to such medication as would be useful in the particular application. No one of ordinary skill in the art would use any other kind of medicament and there is no practical way to restrict the claim language so as to exclude all inoperative or deleterious medicaments other than by the addition of such redundant terms as "suitable" or "operative for the purposes described." We dealt with similar arguments in In re Myers, 56 CCPA 1129, 410 F.2d 420, 161 USPQ 668, 672 (1969), and in dealing with an undue breadth rejection said:
>
> > If every element in a mechanical combination claim were required to be so specific as to exclude materials known to be inoperative and which even

> those not skilled in the art would not try, the claims would fail to comply with 35 U.S.C. 112 [second paragraph] because they would be so detailed as to obscure, rather than [to] particularly point out and distinctly claim, the invention.
>
> We are here dealing with combination claims, not with claims for medicaments per se. It is always possible to put something into a combination to render it inoperative. It is not the function of claims to exclude all such matters but to point out what the combination is. We consider this ground of rejection unsound and will not sustain it.

The applicants submit that the decision of the Anderson Court, i.e., that claims do not fail to satisfy the enablement requirement merely because they possibly cover non-enabled embodiments, is supportive of the patentability of the applicants claim 17.

The Examiner is further requested to appreciate the following comments of the Court in In re Anthony, 162 USPQ 594, 606 (C.C.P.A. 1969):

> That further research may be necessary before the claimed compositions are once again marketed on a commercial scale is not really material to whether those compositions are now useful, nor is it fatal to appellant's case. See Land v. Regan 52 CCPA 1048, 342 F.2d 92, 144 USPQ 661 (1965). As appellant points out, [15] one of the fundamental purposes of the patent system, as recognized by the recent Report of the President's Commission on the Patent System, is to stimulate, in the Commission's words, "the investment of additional capital needed for the further development and marketing of the invention." To deny appellant his patent grant because further research and development may be necessary before marketing may again take place would effectively defeat that objective of the patent system.
> [fn. 15] He also states:
> The most important consequence of the grant of a patent in this case is that it would tend to encourage the assignee or a licensee of the assignee to do further work to determine, inter alia, whether the claimed invention is in fact responsible for the side effect or whether a New Drug Application can be obtained with due consideration for the possible side effect

> in spelling out indications for use of the invention. This is the kind of investment the patent system was intended to encourage. This is the kind of investment that will best serve the public in providing safe medicaments to alleviate mankind's ever present medical problems.

The Examiner's suggestions that *in vivo* clinical data is required to support the claimed medicament is believed to be contrary to the above-quoted comments of the Anthony Court .

The specification, taken with the advanced level of skill in the present art, adequately describes how to make and use the claimed invention. The specification is directed to one of ordinary skill in the art. The possibility that the Examiner can articulate alleged non-enabled uses for the claimed product fails to support a conclusion that the specificaiton fails to enable the rejected claim.

The successful use of HCV envelope proteins or portions thereof as medicaments is known in the art. The applicants believe that U.S. Patent No. 6,635,257 (which includes a claim to a method of inducing immunity against HCV in a chronic HCV carrier) , and specifically Examples 4-6 of same, provide evidence of the advanced level of skill in the art. Moreover, U.S. Patent No. 7,101,561 (which includes claims to methods of preventing evolution to chronic infection of a HCV infection in a mammal), and specifically Examples 15-18 of same, and U.S. Patent Application Publication No. 2004-0126395 A1, and specifically, for example, Examples 19-21 of same, further evidence the advanced level of skill in the art.

The Examiner is further requested to see, for example, Example 23 and Fig. 52 of the assignee's U.S. Patent No. 7,048,930 (which includes claims to medicaments),

wherein antibodies in mice were induced by HCV viral-like particles (VLPs) formed of sulphonated E1 compared to VLPs formed of alkylated E1.

The applicants again submit that there is ample evidence and teaching for one of ordinary skill in the art to make and use HCV envelope proteins as an immunogenic composition to produce an immune response which is more likely than not to be beneficial in ameliorating infection or treating disease. One of ordinary skill in the art will appreciate that such compositions are operable embodiments of medicaments, as claims in U.S. Patent No. 7,048,930, without functional limitation.

The claims, including new claim 34, are submitted to be supported by an enabling disclosure. Withdrawal of the Section 112, first paragraph "enablement", rejection of claim 17 is requested.

The obviousness-type double patenting rejection of claims 12-20 and 22-33 over claims 1-4, 16 and 34 of U.S. Patent No. 7,048,930 is obviated by the attached Terminal Disclaimer and fee. Entry of the attached and withdrawal of the rejection are requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required.

Respectfully submitted,

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